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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,873	07/03/2006	Rachel Butler	T3140(C)	9573
	7590 05/19/201 TENT GROUP	EXAMINER		
800 SYLVAN AVENUE			NEGRELLI, KARA B	
AG West S. Wi ENGLEWOOD	ng CLIFFS, NJ 07632-31	100	ART UNIT	PAPER NUMBER
			1796	
			NOTIFICATION DATE	DELIVERY MODE
			05/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)		
	10/566,873	BUTLER ET AL.		
Office Action Summary	Examiner	Art Unit		
	KARA NEGRELLI	1796		
The MAILING DATE of this communication ap Period for Reply	ppears on the cover sheet wit	h the correspondence address		
· ·	IVIQ SET TO EVDIDE 2 MC	NITH(S) OR THIRTY (20) DAVS		
A SHORTENED STATUTORY PERIOD FOR REPWHICHEVER IS LONGER, FROM THE MAILING I - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailling date of this communication. - If NO period for reply is specified above, the maximum statutory perior. - Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC 1.136(a). In no event, however, may a re d will apply and will expire SIX (6) MONT tte, cause the application to become ABA	ATION. oly be timely filed HS from the mailing date of this communication. NDONED (35 U.S.C. § 133).		
Status				
1)⊠ Responsive to communication(s) filed on <u>06</u> .	<u>April 2010</u> .			
2a) This action is FINAL . 2b) ☐ Th	is action is non-final.			
3) Since this application is in condition for allow	ance except for formal matte	rs, prosecution as to the merits is		
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D.	11, 453 O.G. 213.		
Disposition of Claims				
4)⊠ Claim(s) <u>1-30</u> is/are pending in the applicatio	n.			
4a) Of the above claim(s) 7,11 and 22 is/are v	withdrawn from consideratior	1.		
5) Claim(s) is/are allowed.				
6)⊠ Claim(s) <u>1-6,8-10,12-21 and 23-30</u> is/are reje	ected.			
7) Claim(s) is/are objected to.				
8) Claim(s) are subject to restriction and	or election requirement.			
Application Papers				
9)☐ The specification is objected to by the Examir	ner.			
10)☐ The drawing(s) filed on is/are: a)☐ ac	ccepted or b) objected to b	y the Examiner.		
Applicant may not request that any objection to th				
Replacement drawing sheet(s) including the corre				
11) The oath or declaration is objected to by the E	examiner. Note the attached	Office Action or form P1O-152.		
Priority under 35 U.S.C. § 119				
12)⊠ Acknowledgment is made of a claim for foreig a)⊠ All b)□ Some * c)□ None of:	n priority under 35 U.S.C. §	119(a)-(d) or (f).		
1. Certified copies of the priority docume	nts have been received.			
2. Certified copies of the priority docume	•	· · · · · · · · · · · · · · · · · · ·		
3. Copies of the certified copies of the priority documents have been received in this National Stage				
application from the International Bure		- a - time of		
* See the attached detailed Office action for a lis	st of the certified copies not r	eceivea.		
Attachment(s)				
1) Notice of References Cited (PTO-892)		immary (PTO-413)		
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)		/Mail Date ormal Patent Application		
Paper No(s)/Mail Date	6) 🔲 Other:			

Application/Control Number: 10/566,873 Page 2

Art Unit: 1796

POROUS MATERIAL AND METHOD OF PRODUCTION THEREOF

DETAILED ACTION

Response to Amendment

- 1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 2. Any rejections stated in the previous Office Action and not repeated below are withdrawn.
- 3. The new grounds of rejection set forth below are necessitated by applicant's amendment filed on April 3, 2010. In particular, claim 1 has been amended to recite "...and said matrix building material is a water soluble polymeric material." Claims 7 and 11 have been cancelled. Claim 22 was previously cancelled.
- 4. It is noted that no new prior art has been applied to previously rejected claims. The rejections have been modified to reflect the incorporation of dependent claims 7 and 11 into claim 1. For this reason it is proper to make the present action FINAL.

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Art Unit: 1796

6. Claims 1-6, 8-10, 12-21, and 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko et al. (US 2003/0134918) and further in view of Butler et al. (Advanced Materials, "Emulsion Templating Using High Internal Phase Supercritical Fluid Emulsions."

- 7. Ko et al. teach compositions comprising replacing the oil in an oil-in-water emulsion with supercritical fluids, such as CO₂, that are non-toxic, environmentally friendly, more soluble, and cost effective (paragraph [0007]). After polymerization, the CO₂ is easily extracted from the polymer as a gas (paragraph [0008]). The supercritical CO₂ causes swelling of the polymeric matrix, allowing diffusion of surface active agents or other active components into the matrix in the swollen state, wherein upon depressurization, the matrix deswells and entraps the active components to modify properties of the foam (paragraph [0008]). By controlling the nature of the emulsion, and the polymerization process, nanopores can be created (paragraph [0008]). Ko et al. further teach that by depressurization, the CO₂ is vented away, and all or a portion of the oil phase is removed (paragraph [0044]).
- 8. Solvents, particularly those used in the liquid form, can be removed by freezedrying (meaning the aqueous phase would at this point be at least partially frozen) (paragraph [0032]). Ko et al. do not expressly teach reducing the temperature of the emulsion to a range of from -5°C to -30°C. However, since Ko et al. teach freeze-drying the composition to remove solvent in a process which involves first freezing the substance and then subliming it (paragraph [0032]), one of ordinary skill in the art would

Art Unit: 1796

recognize that freezing includes exposing the substance to temperatures which fall within the instantly claimed range.

- 9. Operations such as vacuum removal, removal driven by air pressure, pressing the foam, or other methods can be used to remove the oil phase, the supercritical fluid, remaining water, emulsifier, initiators, or any other unpolymerized material from the foam (i.e. there would be no solvent residue remaining in the material) (paragraph [0044]).
- 10. Ko et al. further teach the use of surfactants such as polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monopalminate (Tween 40) (paragraph [0021]). Further additives can also be used in the composition, such as solid metal nanoparticles (pertaining to instant claims 2-6 and 19-20), such as hydrophilic titanium oxide, silica, and the like (paragraph [0048]), as well as copper hydroxide or zinc hydroxide (organic reagents) as antimicrobial and/or odor control agents (paragraph [0065]).
- 11. Examples of the monomers to be polymerized for the composition of Ko et al. include polycarboxylic acid such as acrylic acid, vinyl lactams, aromatic vinyl sulfonic acids, carboxylic acid salt-containing monomers, N-hydroxyalkyl acrylamides (polyacrylamides, which the instant application recognizes is a water soluble matrix building material), methyacrylic sulfonic acids, or acrylic sulfonic acids, (paragraph [0053]). The monomers are to be dispersed within the water phase of the invention (paragraph [0053]). The composition of may further comprise cellulosic fibers (paragraph [0049]). Because Ko et al. teach that these water soluble polymers may be

Art Unit: 1796

dispersed in the aqueous phase of the emulsion, and because Ko et al. teach that carbon dioxide may completely substituted for the oil phase in a water-in-oil HIPE emulsion, and because crosslinking agents *may* be added to the composition (making them optional), the compositions of Ko et al. may be water-soluble porous materials. Ko et al. also teach that the porous materials may be molded into any desired shape (paragraph [0068]) (which would include a monolithic block, as described in claims 17 and 25).

- 12. As to instant claims 17-18, case law holds that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). It is the examiner's position that the porous products of Ko et al. are capable of being formed into "any desired shape," and are not structurally different than the instant invention. "Any desired shape" would include a monolithic block or particles or beads.
- 13. Ko et al. further teach that the polymeric foam is used to produce absorbent articles (paragraph [0063]), including bandages or wound dressings (wound healing matrices) (paragraph [0010]).
- 14. The foams produced according to the invention of Ko et al. have pore volumes of from 6 cc/g to 200 cc/g. The bulk density would therefore be 1/200 g/cc to 1/6 g/cc, or from 0.005 to 0.16 g/cc (paragraph [0028]). The polymeric foam further has an average

Art Unit: 1796

cell size of 50 microns or less (paragraph [0038]). These ranges overlap the values given in instant claim 23.

Page 6

- 15. It is well settled that where the prior art describes the components of a claimed compound or compositions in concentrations within or overlapping the claimed concentrations a prima facie case of obviousness is established. See *In re Harris*, 409 F.3d 1339, 1343, 74 USPQ2d 1951, 1953 (Fed. Cir 2005); *In re Peterson*, 315 F.3d 1325, 1329, 65 USPQ 2d 1379, 1382 (Fed. Cir. 1997); *In re Woodruff*, 919 F.2d 1575, 1578 16 USPQ2d 1934, 1936-37 (CCPA 1990); *In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974).
- 16. It is noted that while 24-25 claim a water soluble porous material, all elected claims are recited in the product-by-process format by use of the language, "A water soluble porous material being produced in the form of..." Case law holds that:

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

- 17. To the extent that the process limitations in a product-by-process claim do not carry weight absent a showing of criticality, the reference discloses the claimed product in the sense that the prior art product structure is seen to be no different from that indicated by the claims.
- 18. Ko et al. do not expressly teach that the porous material of the invention is substantially free of cross-linking. However, Ko et al. teach that crosslinking materials are optional components (paragraph [0038]).

Art Unit: 1796

19. Ko et al. also do not expressly teach that method for producing the porous materials comprises from 5-20% w/v of matrix building material, from 5-20% w/v surfactant in respect of water, and 65-95% CO₂.

Page 7

20. However, Butler et al. (2001) (Advanced Materials 2001, 13, 1459-1463) teaches CO₂-in-water emulsions comprising 70% to 80% CO₂, 10% w/v poly (vinyl alcohol) relative to water, and 1 to 10% surfactant w/v based on water (page 1460, column 2, paragraph 2, lines 1-4 and page 1461, paragraph 2, lines 5-8). It would have been obvious for one of ordinary skill in the art to use the concentrations of each component as specified by Butler et al. (Advanced Materials 2001, 13, 1459-1463) in the invention of Ko et al. because using the concentrations results in a system in which free-radical polymerization occurs before the emulsion becomes destabilized (Butler et al., Advanced Materials 2001, 13, page 1460, column 2, paragraph 2, lines 9-12). Addition of polyvinyl alcohol further counteracts destabilization when added to the aqueous phase of the emulsion before polymerization, resulting in an emulsion sufficiently stable for producing open-cell porous materials (Butler et al., Advanced Materials 2001, 13, page 1461, column 1, paragraph 2, lines 5-12). While Butler et al. teach that crosslinked acrylamide based polymers may be used to produce the porous materials, Butler et al. further teach that the invention may be applied to a much wider range of materials (page 1460, paragraph 3), such as 2-hydroxyethyl acrylate. The substitution of acrylamide with 2-hydroxyethyl acrylate led to porous, open-cell materials suggesting that the technique described by Butler may be applied to a wide range of hydrophilic and hydrogel materials. Butler also teaches that water-soluble materials are desirably

Art Unit: 1796

used in the formation of the materials of the invention, see phage 1460, third full paragraph.

21. Both Butler et al. and Ko et al. are from the same field of endeavor: porous materials such as foams produce using CO₂ –in- water- emulsions. (See paragraph [00008] in Ko et al. and the first full paragraph of Butler et al., *Advanced Materials 2001*, 13, page 1460). It would have been obvious for one of ordinary skill in the art to use the materials of Butler et al. in the method of Ko et al. because the materials of Butler et al. lend to defined porous structures without the use of any volatile organic solvents. Additionally, paragraph [0009] of Ko et al. teaches that the "Emulsion Templating Using Supercritical Fluid Emulsions" article by Butler et al. is incorporated by reference, as the technologies of Butler et al. can be adapted to improved HIPE polymerization processes used in the production of foams for absorbent articles, particularly using supercritical carbon dioxide to replace the oil phase in the HIPE foam-production processes to produce foams having higher capillary tension or other improved physical and interfacial properties relative to past HIPE foams.

Response to Arguments

- 22. Applicant's arguments filed April 6, 2010 have been fully considered but they are not persuasive.
- 23. Applicant argues that the crux of the argument rests on the assertion that addition of a crosslinking agent to the emulsion in Ko et al. is an optional step, and therefore because water soluble polymers are "dispersed in the agueous phase of the

Art Unit: 1796

emulsion...the compositions of Ko et al. may be water soluble porous materials."

Applicant asserts that the interpretation of the examiner "cherry picks" part of the text of Ko et al. instead of viewing the reference as a whole. Applicant states that Ko et al. incorporates by reference the teachings of US 5,652,194; US 5,260,345; US 5,817,704,; and US 5,268,224. Applicant states that each of the references teaches a water-insoluble crosslinking agent.

- 24. While it is noted that Ko et al. may incorporates the above US Patents by reference, this does take away from the teachings of Ko et al. which recite that a crosslinking agent *may* be added to the composition of the invention. Applicant further argues that paragraph [0022] of Ko et al. refers to crosslinking monomers and not crosslinking agents. Applicant argues that a crosslinking monomer is a moiety having at least two polymerizable, unsaturated groups in its molecular unit and such crosslinking monomers will *self-crosslink*.
- 25. Applicants' attention is again drawn to the language used in the Ko et al. reference. Paragraph [0022] recites that the cross-linking monomers of the invention *may* undergo self-crosslinking or a crosslinking agent *may* be added to crosslink the polymerized material. Use of this language implies that the components are not essential as indicated by the arguments of the applicant. In fact, no where in Ko et al. is there a teaching the crosslinkers are essential or critical in the material of the invention. The recitations regarding crosslinking materials teach that cross-linking monomers of the invention *may* undergo self-crosslinking or a crosslinking agent *may* be added to crosslink the polymerized material. As discussed in the rejection above, Ko et al.

Application/Control Number: 10/566,873 Page 10

Art Unit: 1796

teaches that the polymers of the invention may comprise water-soluble polymeric materials to be used in the C/W emulsion.

- 26. Applicant argues that paragraph [0044] teaches the removal of water-soluble materials or lose fibers. Paragraph [0044] teaches that any excess component *can* be removed, if desired. Paragraph [0044] does not teach that removal of water-soluble materials is a required step in the formation of the materials of the invention.
- 27. Applicant argues that Sample 4 of Butler produces a crosslinked, polymeric foam, regardless of the fact that that one of the monomers is water soluble prior to its polymerization.
- 28. Applicants' argument is not persuasive. Note that while Butler et al. do not disclose <u>all</u> the features of the present claimed invention, Butler et al. is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, 5-20% w/v of matrix building material, from 5-20% w/v surfactant in respect of water, and 65-95% CO₂, and in combination with the primary reference, discloses the presently claimed invention.

Conclusion

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

30. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA NEGRELLI whose telephone number is (571)270-7338. The examiner can normally be reached on Monday through Friday 9:30 am EST to 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571)272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Application/Control Number: 10/566,873 Page 12

Art Unit: 1796

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/KARA NEGRELLI/ Examiner, Art Unit 1796

/RANDY GULAKOWSKI/ Supervisory Patent Examiner, Art Unit 1796